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| 10/698,424   | 11/03/2003  | David W. Johnson     | CALW-004/01US<br>306562-2009 | 1511             |
| 58349  | 7590        | 05/06/2010           | EXAMINER                     |                  |
| COOLEY LLP<br>ATTN: Patent Group<br>Suite 1100<br>777 - 6th Street, NW<br>WASHINGTON, DC 20001 |             |                      | ROBINSON, KEITH O NEAL       |                  |
|  |             |                      | ART UNIT                     | PAPER NUMBER     |
|  |             |                      | 1638                         |                  |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/698,424

**Applicant(s)**

JOHNSON ET AL.

**Examiner**

KEITH O. ROBINSON

**Art Unit**

1638

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 December 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 2-4, 6-19, 30 and 31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-4, 6-19, 30 and 31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Applicant's cancellation of claims 1, 5 and 20-29, amendment of claims 16, 18 and 19 and addition of new claims 30 and 31, filed December 7, 2009, have been received and entered in full.

Claims 2-4, 6-19, 30 and 31 are under examination.

### ***Response to Arguments***

Applicant's arguments, see pages 14-16 of 'Remarks' filed December 7, 2009, with respect to the 35 USC § 103 rejection on pages 9-11 of the Office Action mailed June 5, 2009 have been fully considered and are persuasive. The rejection has been withdrawn.

### ***Specification***

The disclosure is objected to because of the following informalities: Page 15, Table 1 recites 'CW 83201' in the title; however, the table shows variety 'CW 83021'. This mistake is found throughout the specification in other tables and Applicant is required to make the appropriate corrections for the other tables having this mistake. New matter must be avoided.

### ***Claim Rejections - 35 USC § 112, first paragraph – Written Description***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2-4 and 6-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims read on any *Medicago sativa* alfalfa variety having 8% or greater faster recovery after spring green-up or after harvest and 15% or greater more erect stems at late bloom compared to a recited adapted check.

The specification teaches four alfalfa varieties having the claimed characteristics wherein said varieties were developed using French lines in the initial step (see pages 25-45). The specification teaches that French types of alfalfa include Flemish and the Flemish type alfalfa varieties, which are characterized as being fast to recover after cutting (see page 4, lines 17-22).

*Medicago sativa* alfalfa varieties having 8% or greater faster recovery after spring green-up or after harvest and 15% or greater more erect stems at late bloom compared to an adapted check are not supported by the disclosure of alfalfa varieties having the claimed characteristics wherein said varieties were not developed using French lines, because Applicant has only provided evidence that French lines were used in the initial cross to produce alfalfa plants with the claimed characteristics. There is no evidence in the disclosure or anywhere else in the record showing Applicant conveyed that any other alfalfa was suitable for producing alfalfa with the claimed characteristics other than French lines.

Though Applicant discloses four alfalfa varieties with the claimed characteristics in the instant specification, one of skill in the art would not recognize that Applicant was in possession of the genus of *Medicago sativa* plants as claimed. Applicant is claiming any *Medicago sativa* alfalfa plant with the claimed characteristics, but the instant specification discloses alfalfa with the claimed characteristics having the common attribute of using French lines in the initial step. Thus, Applicant has only shown possession of and adequately described alfalfa plants having the claimed characteristics wherein said plants were derived using French lines as an initial step.

Page 4 of the specification indicates that Flemish-type alfalfa varieties are characterized as being fast to recover after cutting. The specification does not indicate that any other types of alfalfa have the characteristics listed in the claims. The alfalfa varieties discussed in the working examples were all derived from French type alfalfa plants. The specification does not correlate the function of having 8% or greater faster recovery after spring green-up or after harvest, or 15% or greater more erect stems at late bloom, with alfalfa plants other than those derived from French type alfalfa.

### ***Response to Arguments***

Applicant argues that the USPTO did and does issue claims to seed lines with particular characteristics and uses U.S. Patent No. 5,602,313 as an example (see page 8, 1<sup>st</sup> and 2<sup>nd</sup> paragraphs of 'Remarks' filed December 7, 2009).

This is not persuasive. Each patent application is examined on its own merits. It is also noted that the cited patent was allowed before the written description guidelines were revised. Thus, Applicant's argument is irrelevant to the instant case.

Applicant argues that they are not claiming just any *Medicago sativa* alfalfa plant with faster recovery and more erect stems, but rather are claiming *Medicago sativa* alfalfa varieties with 8% or greater faster recovery after spring green-up or after harvest coupled with 15% or greater more erect stems at late bloom when compared to specific commercial check varieties (see page 8, 3<sup>rd</sup> paragraph of 'Remarks' filed December 7, 2009).

This is not persuasive. As stated above, the specification shows that a common attribute of the disclosed alfalfa varieties is the use of French lines in the initial step to produce the claimed invention and that it is these lines that provide the claimed characteristics, particularly, fast recovery. However, Applicant is claiming all *Medicago sativa* alfalfa varieties having the claimed characteristics, even those which do not comprise French lines in their genetic background.

Applicant argues that the specification provides detailed written description of the development of at least four very different and distinct *Medicago sativa* alfalfa varieties derived from diverse genetic background, wherein each variety meets the limitations of the claims (see page 9, 2<sup>nd</sup> paragraph of 'Remarks' filed December 7, 2009).

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This is not persuasive. As discussed above, Applicant has only shown possession of and adequately described alfalfa plants having the claimed characteristics wherein said plants have French type germplasm and the specification teaches that the four varieties that are described have the common attribute of French lines used in the initial step to produce the varieties. Further, the seed of all four varieties that Applicant refers to have been deposited.

Applicant argues that one skilled in the art can use any of Applicant's inventive, disclosed and deposited alfalfa varieties to develop additional alfalfa varieties which meet the claimed limitations and that the 'Johnson Declaration' clearly demonstrates that Applicant has done exactly this (see page 10, 1<sup>st</sup> paragraph).

This is not persuasive. The claims are not limited to any of the deposited lines or to any methods of using said lines to produce the claimed invention.

***Claim Rejections - 35 USC § 112, first paragraph - Enablement***

Claims 2-4, 6-19, 30 and 31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims read on any *Medicago sativa* alfalfa variety having 8% or greater faster recovery after spring green-up or after harvest and 15% or greater more erect stems at late bloom compared to an adapted check.

*In re Wands*, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples of the invention, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

(1) the breadth of the claims

The claims are broadly drawn to a *Medicago sativa* alfalfa variety having 8% or greater faster recovery after spring green-up or after harvest and 15% or greater more erect stems at late bloom compared to an adapted check; however, the specification discloses *Medicago sativa* alfalfa varieties having 8% or greater faster recovery after spring green-up or after harvest and 15% or greater more erect stems at late bloom compared to an adapted check variety wherein said variety comprises French alfalfa germplasm.

(2) the nature of the invention



The invention is drawn to a *Medicago sativa* alfalfa variety having 8% or greater faster recovery after spring green-up or after harvest and 15% or greater more erect stems at late bloom compared to an adapted check.

(3) the state of the prior art

The state of the prior art does not teach *Medicago sativa* alfalfa varieties with 8% or greater faster recovery after spring green-up or after harvest and/or 15% or greater more erect stems at late bloom compared to an adapted check.

(4) the relative skill of those in the art

The relative skill in breeding art is high.

(5) the predictability or unpredictability of the art

It is predictable for one skilled in the art to make the claimed invention because there is no information of the identity of the French lines used in the working examples nor is there any indication that other alfalfa lines can be used to produce the claimed invention. It is also unknown what other alfalfa types can be used to produce the claimed plants.

(6) the amount of direction or guidance presented

The specification does not provide any guidance regarding the French lines used to produce the claimed invention and it is unclear if all French lines could be used to produce the claimed invention. It is also unclear if the French

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lines used to produce the claimed invention are available to the public. It is noted that seed of the four alfalfa varieties, CW 7506, CW83201, CW85029, and CW95026, disclosed in the working examples have been deposited with the ATCC.

(7) the presence or absence of working examples of the invention

The specification only provides working examples of alfalfa varieties having the claimed characteristics wherein said varieties comprise French germplasm in their genetic background. There are no working examples with regard to other *Medicago sativa* plants not comprising French alfalfa germplasm. Further, the French varieties used in the working examples are not identified.

(8) the quantity of experimentation necessary

The quantity of experimentation necessary to make and use the claimed invention is undue because the specification does not provide any guidance regarding the French lines used in the initial step to produce the claimed invention. It is unclear if these lines are publicly available and it is unclear if all French types of alfalfa possess the claimed characteristics.

Thus, based on the breadth of the claims, the unpredictability of the art with regard to the characteristics of French alfalfa types, the presence of working examples each disclosing the use of French alfalfa types in the development of alfalfa varieties with the claimed characteristics and the guidance of the specification disclosing using unidentified French alfalfa types in producing the

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claimed invention, it would require undue experimentation for one of skill in the art to make and use the claimed invention using any other alfalfa line as an initial step in producing the claimed invention.

### ***Response to Arguments***

It is noted that Applicant has provided a deposit statement with regard to the deposited lines (see page 11, 1<sup>st</sup> paragraph of 'Remarks' filed December 7, 2009); however, the statement needs to be corrected to replace "effective" in line 2 of step (c) with "enforceable" to satisfy the deposit. Once the deposit statement has been perfected the claims will be enabled only for those deposited varieties.

In addition, it is unclear if one skilled in the art would be able to follow the method disclosed in the specification using other types of alfalfa lines, to produce the claimed invention nor is it clear if one skilled in the art would be able to use any French type alfalfa line in the method disclosed in the specification to produce the claimed invention.

Applicant argues that alfalfa breeding is predictable and have provided a clear and detailed plant breeding roadmap to accomplishing the claimed invention and deposited germplasm that provides the claimed traits (see page 11, last paragraph to page 12, 1st paragraph of 'Remarks' filed December 7, 2009).

This is not persuasive. It is unclear if one skilled in the art would have been able to use the plant breeding roadmap provided in the specification because it is unclear which French lines were used in the initial step and it is

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unclear if said lines are publicly available. In addition, it is unclear if all French lines would convey the claimed characteristics cited in the claimed invention (i.e., 8% or greater faster recovery after spring green-up or after harvest and 15% or greater more erect stems at late bloom compared to an adapted check).

Applicant argues that they have demonstrated that the disclosed methods were used to develop at least four different, distinct *Medicago sativa* alfalfa varieties possessing the claimed traits (see page 12, 2<sup>nd</sup> paragraph of 'Remarks' filed December 7, 2009).

This is not persuasive. See above arguments regarding French lines.

### ***Claim Rejections - 35 USC § 102/103***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 2-4, 6-19, 30 and 31 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Cluff et al (U.S. Patent No. 6,143,951, November 7, 2000).

The claims read on any *Medicago sativa* alfalfa varieties with 8% or greater faster recovery after spring green-up or after harvest coupled with having 15% or greater more erect stems at late bloom when compared to an adapted commercial check variety.

Cluff et al teach a *Medicago sativa* alfalfa line, WL-C290, that has very fast recovery after harvest and excellent standability under sprinkler irrigation (see column 17, lines 37-38). Excellent standability is interpreted as high standability as defined on page 14, line 2 of the specification which is equivalent to more erect stem.

The Office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same, material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the Applicant to provide that the claimed product is different from those taught by the prior art and to establish patentable differences. See *in re Best* 562F.2d 1252 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

The alfalfa plant taught by the prior art differs from the claimed alfalfa plant only in their method of making, namely by the use of different parental material in

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the prior art. However, the method of making the claimed alfalfa plant would not distinguish it from the prior art alfalfa plant.

See *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejectable over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products.

See *In re Best*, 195 USPQ 430, 433 (CCPA 1997), which teaches that where the prior art product seems to be identical to the claimed product, except that the prior art is silent as to a particularly claimed characteristic or property, then the burden shifts to Applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention.

### ***Response to Arguments***

Applicant argues the 'Reich Declaration' provides experimental data to demonstrate that alfalfa plant of the cited reference, 'WL-C290', is susceptible to lodging under sprinkler irrigation and alfalfa variety CW 95026 had significantly more resistance to lodging than WL-C290 (see page 16, last paragraph to page 17, 2<sup>nd</sup> paragraph of 'Remarks' filed December 7, 2009).

This is not persuasive. The 'Reich Declaration' does not provide any data to demonstrate that the plant of the cited reference, WL-C290, did not have 15% or greater more erect stems at late bloom compared to an adapted check variety as determined by the method of step (b), steps 1-5. The data provided by the 'Reich Declaration' fails to demonstrate that the differences in results are

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unexpected and unobvious and of both statistical and practical significance because it does not compare the claimed plants with the cited reference plant using the claimed steps used to determine percentage of erect stems.

### ***Conclusion***

No claims are allowed.

### ***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KEITH O. ROBINSON whose telephone number is (571)272-2918. The examiner can normally be reached Monday – Friday, 8:00 a.m. - 4:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Keith O. Robinson

/Ashwin Mehta/  
Primary Examiner, Art Unit 1638